ANDERSON EXHIBIT 10G

PHARMACEUTICAL MANUFACTURERS WARRICK AND DEY's USE OF THE "SPREAD" TO CAPTURE THE STATE OF FLORIDA'S MEDICAID MARKET FOR ALBUTEROL 0.083%

D-8

Manufacturer	True Cost per ml	Florida Medicaid Reimbursement per ml	The "Spread"	# of claims	Reimbursement paid by Florida Medicaid
Warrick	$0.1065	$0.3590	$0.2525	12,673	$763,595.42
Dey	$0.1125	$0.3531	$0.2406	9,792	$707,220.50
Zenith/Goldline	N/A	$0.2138	**	102	$4,981.86
Geneva	N/A	$0.1787	**	19	$1,278.08
TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA MEDICAID PROGRAM (January 1 through March 31, 1997)					$1,477,075.86

**, THE USE OF THE "SPREAD" TO CAPTURE MARKET SHARE IS EVIDENCED BY THE FACT THAT WARRICK'S AND/OR DEY'S CUSTOMERS WILL RECEIVE MORE PROFIT BY PURCHASING WARRICK'S AND/OR DEY'S ALBUTEROL THAN IF ZENITH/GOLDLINE OR GENEVA GAVE THEIR CUSTOMERS THEIR ALBUTEROL FOR FREE.

Ipratropium Bromide 0.02% Sol.

HCPCS code J7645 & (K0518)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	Ven-A-Care COST PER MEDICARE UNIT	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE ALLOWABLE $
1995	$ 3.11 mg. ($0.62/ml)	$3.11	$0.00	0%	$14,426,108
1996	$ 3.75 mg. ($0.75/ml)	$3.26	$0.49	15%	$47,388,622
1997	$ 3.50 mg. ($0.70/ml)	$2.15	$1.35	63%	$96,204,639
1998	$ 3.34 mg.	$1.70	$1.64	96%	$176,887,868
1999	$ 3.34 mg.	$1.60	$1.74	108%	$253,400,414
2000	$ 3.34 mg.	$0.94	$2.40	255%	$347,527,960
2001	$ 3.34 mg.	$0.82	$2.52	307%	

* Medicare Units were converted from ml's to mg's for the years 1996,1996 &1997 (5 ml=1 milligram) & 1998-2001 @ 95% of AWP

P-1

Ipratrop-Medicare-01.wpd

Albuterol Sulfate 0.083%
HCPCS codes J7619 & (K0505)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	Ven-A-Care COST PER MEDICARE UNIT	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE ALLOWABLE $
1994	$ 0.492 mg. ($0.41/ml)	$ 0.38	$ 0.113	29%	$147,867,789
1995	$ 0.516 mg. ($0.43/ml)	$ 0.244	$ 0.272	111%	$166,901,971
1996	$ 0.492 mg. ($0.41/ml)	$ 0.244	$ 0.248	101%	$178,411,078
1997	$ 0.492 mg. ($0.41/ml)	$0.19	$ 0.303	160%	$199,763,937
1998	$ 0.47 mg.	$ 0.16	$ 0.31	193%	$230,376,027
1999	$ 0.47 mg.	$ 0.14	$ 0.33	233%	$248,844,463
2000	$ 0.47 mg.	$ 0.08	$ 0.39	487%	$295,661,130
2001	$ 0.47 mg.	$ 0.07	$0.40	571%	

* Medicare Units were converted from ml's to mg's for the years 1994-1997
(3 ml = 2.6 milligram) &
1998-2001 @ 95% of AWP

Albuterol-01-Medicare.wpd

P-2

DEPARTMENT OF HEALTH & HUM

Office of Inspector General

Q1

Memorandum

Date DEC 13 1999

From June Gibbs Brown
Inspector General

Subject Infusion Therapy Services Provided in Skilled Nursing Facilities (A-06-99-00058)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached are two copies of our final report entitled, "Infusion Therapy Services Provided in Skilled Nursing Facilities." The objective of this audit was to determine if infusion therapy services provided by some infusion suppliers to Medicare-reimbursed skilled nursing facilities (SNF) were reasonably priced, medically necessary, and classified correctly on the cost reports. Our review of three infusion suppliers, for the period 1995 through 1998, showed they provided infusion therapy services to Medicare-reimbursed SNFs that were excessively priced and unnecessary. In addition, the three infusion suppliers billed certain infusion services incorrectly, causing those costs to be misclassified on the SNFs' cost reports. This occurred because the reimbursement system was vulnerable to abusive billing schemes. As a result, patients were placed at undue risk, Medicare overpaid the SNFs, and the overpayments may have been included in the base year costs used to establish the prospective payment system (PPS) rates.

The three infusion suppliers reviewed charged SNFs excessive prices for infusion therapy, provided unnecessary infusion services to SNF patients, and improperly billed SNFs for nursing services that the SNFs, in turn, misclassified on the Medicare cost reports.

The SNFs billed Medicare for these unallowable costs. To quantify the impact to Medicare, we reviewed claims submitted by 22 SNFs that used various infusion therapy suppliers. The vast majority of infusion services were provided by two of the three infusion therapy suppliers reviewed in this audit. At the 22 SNFs, $4.8 million out of $9 million in claims reviewed (53 percent) were not medically necessary. An additional $332,000 in payments that were found to be medically necessary were questioned because the prices exceeded the prevailing rate. Finally, another $158,000 was questioned because routine costs were misclassified as ancillary costs on the SNF cost reports.

The three infusion therapy suppliers we reviewed accounted for at least $138 million, or approximately 20 percent, of all infusion therapy costs reimbursed by Medicare nationwide during 1995 through 1998. Because these infusion therapy suppliers employed the same

billing practices with hundreds of SNFs in several States, we are concerned that additional unallowable costs were paid by Medicare during this period. We also have concerns that these abusive practices may have resulted in inflated base year costs upon which the PPS rates were based.

In addition to the financial effects we noted above, overutilization and overpricing were potentially harmful to the patients. Medical reviewers who were a part of our audit concluded that patients receiving unnecessary infusion services were placed at undue risk for complications, including increased risk of infection, fluid and electrolyte imbalance, and medical reactions. Furthermore, infusion services are invasive procedures that are painful and, when unnecessary, reduce the quality of life.

One of the three infusion suppliers has entered into a $10 million settlement agreement with the Government to resolve its civil liability under the False Claims Act and Civil Monetary Penalties Law which involved delivery of infusion services in Texas and in other States. The other infusion suppliers and many nursing homes are the subjects of additional audits and investigations by the Office of Inspector General (OIG), the fiscal intermediary, and/or the Federal Bureau of Investigation.

Prior to 1998, Medicare paid nursing homes through a retrospective, reasonable cost-based system. As our results showed, this system was vulnerable to abusive billing schemes because providers were reimbursed based on their costs, thus giving them a strong incentive to provide unnecessary and overpriced services to increase their Medicare payments. Abusive billing arrangements between SNFs and infusion suppliers resulted in tremendous profits which encouraged the overutilization of infusion services when no treatment was necessary.

Section 4432(a) of the Balanced Budget Act of 1997 required implementation of a Medicare PPS for SNFs. In 1998, the Health Care Financing Administration (HCFA) implemented the SNF PPS for cost reporting periods beginning on or after July 1, 1998. Accordingly, payments are no longer based on the reasonable cost-based system, but rather are based on a fixed per diem which is adjusted for the patient's acuity level. The PPS rates were based on mean SNF costs for cost reporting periods beginning in Fiscal Year 1995. Recently, nursing home officials have expressed concern that reimbursements under PPS for high-cost services, including infusion services, are too low and thus quality of care may be compromised. Various alternatives for changing PPS rates are being discussed.

While our audit did not focus on the accuracy of the PPS rates for infusion therapy, we want to bring the results of our audit work to your attention should HCFA decide to change the reimbursement rates. We believe the adoption of PPS should help to correct the problem of SNFs and suppliers engaging in abusive billing schemes to increase Medicare reimbursements. However, PPS rates that do not reasonably reflect the SNFs' costs of providing services could still result in financial windfall to the SNFs. Under PPS, patients

may still be subjected to unnecessary services. This could occur if unnecessary infusion therapy services were performed which may increase the patient's classification of services to a higher payment level within the PPS structure. Thus, more patients may be harmed by unnecessary infusion therapy.

We are concerned that unallowable infusion therapy costs may have resulted in inflated base year costs upon which the PPS rates were based. Furthermore, we believe reimbursement levels for infusion therapy that are too high affect quality of care due to overutilization, just as low reimbursement affects quality of care through underutilization. Therefore, before the PPS rates for infusion therapy are modified, we believe that the unallowable costs identified in this report should be seriously considered.

Accordingly, we recommend that HCFA:

- consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF PPS rates. In addition, if legislative changes are adopted which mandate the use of cost reimbursement for infusion services, work with the OIG to quantify a possible national error rate for infusion therapy services;

- identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS; and

- direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

In response to our draft report, HCFA generally agreed with our recommendations. In response to part of one recommendation, HCFA raised concerns about the benefit of establishing a national error rate for a set of services that is bundled with other sets of services into a single per diem rate under PPS. To take into account HCFA's comments, we changed our report to recommend a national error rate calculation in the event that Congress adopts legislation which mandates the use of cost reimbursement for infusion services. The complete text of HCFA's response is included as Appendix A to the report.

Please advise us within 60 days of actions taken or planned on our recommendations. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06-99-00058 in all correspondence related to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INFUSION THERAPY SERVICES PROVIDED IN SKILLED NURSING FACILITIES

JUNE GIBBS BROWN
Inspector General

DECEMBER 1999
A-06-99-00058

DEPARTMENT OF HEALTH & HUMAN SERVICES — Inspector General

Memorandum

Date DEC 13 1999

From for June Gibbs Brown
Inspector General

Subject Infusion Therapy Services Provided in Skilled Nursing Facilities (A-06-99-00058)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

This final report provides you with the results of our audit of infusion therapy services provided to Medicare beneficiaries residing in skilled nursing facilities (SNF). The objective of the audit was to determine if infusion therapy services provided by some infusion suppliers to Medicare-reimbursed SNFs were reasonably priced, medically necessary, and classified correctly on the cost reports. Our review of three infusion suppliers, for the period 1995 through 1998, showed they provided infusion therapy services to Medicare-reimbursed SNFs that were excessively priced and unnecessary. In addition, the three infusion suppliers billed certain infusion services incorrectly, causing those costs to be misclassified on the SNFs' cost reports. This occurred because the reimbursement system was vulnerable to abusive billing schemes. As a result, patients were placed at undue risk, Medicare overpaid the SNFs, and the overpayments may have been included in the base year costs used to establish the prospective payment system (PPS) rates.

The three infusion suppliers reviewed:

- charged SNFs substantially more than prevailing rates for infusion therapy services;
- provided infusion therapy services to Medicare patients that were not medically necessary; and
- improperly billed the SNFs for nursing services, which the SNFs misclassified as ancillary expenses on their cost reports.

The SNFs, in turn, billed Medicare for these unallowable costs. To quantify the impact to Medicare, we reviewed claims submitted by 22 SNFs that used various infusion therapy suppliers. The vast majority of infusion services were provided by two of the three infusion therapy suppliers reviewed in this audit. At 22 SNFs, $4.8 million out of $9 million in claims reviewed (53 percent) were not medically necessary. An additional $332,000 in payments that were found to be medically necessary were questioned because the prices

exceeded the prevailing rate. Finally, another $158,000 was questioned because routine costs were misclassified as ancillary costs on the SNF cost reports.

The three infusion therapy suppliers we reviewed accounted for at least $138 million, or approximately 20 percent, of all infusion therapy costs reimbursed by Medicare nationwide during 1995 through 1998. Because these infusion therapy suppliers employed the same billing practices with hundreds of SNFs in several States, we are concerned that additional unallowable costs were paid by Medicare during 1995 through 1998. We also have concerns that these abusive practices may have resulted in inflated base year costs upon which the SNF PPS rates were based.

In addition to the financial effects we noted above, overutilization and overpricing were potentially harmful to the patients. Medical reviewers who were a part of our audit concluded that patients receiving unnecessary infusion services were placed at undue risk for complications, including increased risk of infection, fluid and electrolyte imbalance, and medical reactions. Furthermore, infusion services are invasive procedures that are painful and, when unnecessary, reduce the quality of life.

One of the three infusion suppliers has entered into a $10 million settlement agreement with the Government to resolve its civil liability under the False Claims Act and Civil Monetary Penalties Law which involved delivery of infusion services in Texas and in other States. The other infusion suppliers and many nursing homes are the subjects of additional audits and investigations by the Office of Inspector General (OIG), the fiscal intermediary, and/or the Federal Bureau of Investigation.

Prior to 1998, Medicare paid nursing homes through a retrospective, reasonable cost-based system. As our results showed, this system was vulnerable to abusive billing schemes because providers were reimbursed based on their costs, thus giving them a strong incentive to provide unnecessary and overpriced services to increase their Medicare payments. Abusive billing arrangements between SNFs and infusion suppliers resulted in tremendous profits which encouraged the overutilization of infusion services when no treatment was necessary.

Section 4432(a) of the Balanced Budget Act of 1997 (BBA) required implementation of a Medicare PPS for SNFs. In 1998, the Health Care Financing Administration (HCFA) implemented the SNF PPS for cost reporting periods beginning on or after July 1, 1998. Accordingly, payments are no longer based on the reasonable cost-based system, but rather are based on a fixed per diem which is adjusted for the patient's acuity level. The PPS rates were based on mean SNF costs for the cost reporting periods beginning in Fiscal Year (FY) 1995. Recently, nursing home officials have expressed concern that reimbursements under PPS for high-cost services, including infusion services, are too low and thus quality of care may be compromised. Various alternatives for changing PPS rates are being discussed.

While our audit did not focus on the accuracy of the SNF PPS rates for infusion therapy, we want to bring the results of our audit work to your attention should HCFA decide to change the reimbursement rates. We believe the adoption of PPS should help to correct the problem of SNFs and suppliers engaging in abusive billing schemes to increase Medicare reimbursements. However, PPS rates that do not reasonably reflect the SNFs' costs of providing services could still result in financial windfall to the SNFs. Under PPS, patients may still be subjected to unnecessary services. This could occur if unnecessary infusion therapy services were performed which may increase the patient's classification of services to a higher payment level within the PPS structure. Thus, more patients may be harmed by unnecessary infusion therapy.

We are concerned that unallowable infusion therapy costs may have resulted in inflated base year costs upon which the PPS rates were based. Furthermore, we believe reimbursement levels for infusion therapy that are too high affect quality of care due to overutilization, just as low reimbursement affects quality of care through underutilization. Therefore, before the PPS rates for infusion therapy are modified, we believe that the unallowable costs identified in this report should be seriously considered.

Accordingly, we recommend that HCFA:

- consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF PPS rates. In addition, if legislative changes are adopted which mandate the use of cost reimbursement for infusion services, work with the OIG to quantify a possible national error rate for infusion therapy services;

- identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS; and

- direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

In response to our draft report, HCFA generally agreed with our recommendations. In response to part of one recommendation, HCFA raised concerns about the benefit of establishing a national error rate for a set of services that is bundled with other sets of services into a single per diem rate under PPS. To take into account HCFA's comments, we changed our report to recommend a national error rate calculation in the event that Congress adopts legislation which mandates the use of cost reimbursement for infusion services. The complete text of HCFA's response is included as Appendix A.

INTRODUCTION

BACKGROUND

Infusion therapy is growing as an alternative to a wide variety of medical and post-surgical conditions.

Infusion therapy is administered for:

- pain management,
- chemotherapy,
- dehydration,
- feeding, and
- antibiotic treatment.

Frequently SNFs contract with infusion therapy suppliers to purchase infusion services "under arrangement." The infusion therapy suppliers generally provide the drugs, solutions, supplies, and equipment. Some infusion therapy suppliers provide the nursing services to administer the intravenous (IV) solutions at the SNFs.

Prior to the implementation of PPS, the infusion supplier submitted invoices to the SNF for Medicare infusion therapy services. The SNF, in turn, filed a claim with the Medicare fiscal intermediary for these services. The infusion therapy supplier's invoice represented the SNF's cost for the services. The SNF's Medicare claim included the invoiced amount plus an additional charge to cover the SNF's overhead.

From 1995 through 1998, HCFA records showed that SNFs charged Medicare more than $1.4 billion for infusion services. These charges included the costs billed by the infusion suppliers and the additional administrative and general costs billed by the SNFs.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objective

The audit objective was to determine if infusion therapy services provided by some infusion suppliers to Medicare-reimbursed SNFs were reasonably priced, medically necessary, and classified correctly on the cost reports.

Scope

We performed detailed testing of charges associated with infusion drugs and supplies provided by three infusion companies. To quantify the impact to Medicare, we reviewed

claims submitted by 22 SNFs that used various infusion therapy suppliers. The vast majority of infusion services were provided by two of the three infusion therapy suppliers reviewed in this audit. For a chain of 13 SNFs, we selected a statistical sample of 100 claims submitted during 1995 through 1998 out of a universe of 1,133 infusion therapy claims. The 100 infusion claims were tested to determine whether the prices were reasonable, the services were medically necessary, and costs were classified correctly on the cost reports.

In addition, Mutual of Omaha, a Medicare fiscal intermediary, and HCFA medical review staff performed a medical review of another 154 claims from this chain. Finally, Mutual of Omaha performed a medical review of an additional 208 claims from 9 other nursing homes.

We did not review the overall internal control structure of the selected nursing homes. The internal control review was limited to obtaining an understanding of the nursing homes' billing processes. Our tests of internal controls were accomplished through substantive testing.

Methodology

To determine whether services were medically necessary, we obtained the medical records from the facilities and forwarded the records to medical professionals for medical reviews. The medical reviews were performed by physicians with the Texas Medical Foundation, the Medicare peer review organization (PRO) for Texas; nurses at Mutual of Omaha; and a nurse from HCFA. To determine whether the SNFs paid reasonable prices for the infusion services, we obtained pricing information and interviewed officials from 10 infusion companies in Texas to determine a prevailing price. To determine whether infusion services were classified correctly, we reviewed the infusion invoices, interviewed the relevant billing officials at the nursing homes, and traced the invoices to each nursing home's general ledger and cost report.

Field work was performed at four nursing homes in Texas; two infusion supply companies in Texas; Mutual of Omaha corporate headquarters in Omaha, Nebraska; and the OIG Dallas field office. The audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Excessive Prices Were Paid

Infusion therapy suppliers charged SNFs excessive prices for infusion therapy services. The SNFs, in turn, passed these excessive costs on to Medicare under Medicare's retrospective, reasonable cost-based system. Although Medicare imposed a prudent buyer requirement on

the SNFs,[1] there was little incentive for a SNF to obtain the best price. Furthermore, it was resource intensive for the fiscal intermediary to establish the prevailing rate that a prudent buyer should have paid. Consequently, there was little assurance in the cost-based Medicare reimbursement system that an excessive cost would be adjusted downward to reflect the prevailing rate. As a result, Medicare paid substantially more than market rates for infusion services.

Based on a survey of infusion suppliers in Texas, we found that charges for infusion drugs varied widely, from as little as Average Wholesale Price (AWP), which is generally considered a reference price for drugs by the pharmaceutical industry, to more than 20 times AWP. Overall, infusion suppliers in Texas historically charged one to four times AWP for infusion drugs.[2]

The following examples illustrate the excessive prices that infusion suppliers charged SNFs for infusion drugs:

Drug	Cost to SNF	AWP	Percent Difference
Timetin	$155.49	$14.75	1054%
Bactrim	$197.86	$16.00	1237%
Cefotan	$152.57	$11.58	1318%
Vancomycin	$269.76	$15.60	1729%
Mefoxin	$127.24	$12.12	1050%

- One nursing home chain paid an infusion supplier $205 per liter of total parenteral nutrition (TPN) during 1995. The nursing home signed a new infusion contract with the supplier in 1996. After the new contract was executed, the nursing home paid the infusion supplier $1,180 per liter of TPN even though TPN was available from another Texas infusion supplier for $186 per liter. Upon the adoption of Medicare PPS, the infusion supplier lowered its price of TPN from $1,180 per liter to $90 per liter.

- The same infusion supplier charged SNFs more than $460 under the cost reimbursement system for three liters of sodium chloride for hydrating patients. The

[1]Section 2103 of the Provider Reimbursement Manual requires the provider to employ the prudent buyer concept. Specifically, the prudent buyer not only refuses to pay more than the going price for an item or service, but he/she also seeks to economize by minimizing cost. The intermediary excludes excess costs in determining allowable costs under Medicare.

[2]By comparison, Medicare Part B pays significantly less for drugs. Historically, under Medicare Part B, covered prescription drugs were reimbursed at AWP. As of January 1, 1998, Medicare Part B reimburses 95 percent of the AWP for covered prescription drugs.

cost per liter to the infusion supplier was $1.06, or $3.18 for the three liters. Under PPS, the infusion supplier lowered its charges to $15 ($5 per liter) for the same hydration solutions.

Under the cost reimbursement system, SNFs had little incentive to reduce costs. In fact, SNFs had an economic incentive to increase ancillary costs because Medicare reimbursed administrative and general costs to the SNFs based on the share of Medicare expenses incurred by the facilities. Consequently, by paying more for ancillary services, the facilities received additional administrative and general cost reimbursement from Medicare. In addition, suppliers were making such tremendous profits on these services that there was a strong incentive to provide additional services, even though the services were not medically necessary.

Medically Unnecessary Services Were Provided

Infusion therapy suppliers provided infusion therapy services to SNF residents that were not medically necessary. A review by medical professionals of 462 infusion therapy claims submitted by 22 SNFs disclosed that $4.8 million out of $9 million in charges were denied (53 percent).

Because Medicare paid substantially more than the market rate for these infusion therapy services, there was a strong incentive to supply excessive and unnecessary services. Infusion suppliers took a direct interest in patient care. In fact, nurses from the infusion supplier routinely assessed patients when they were admitted to the SNF, and recommended infusion therapy services. As a result, according to the PRO physicians, unnecessary infusion therapy services were performed which put nursing home patients at risk of increased medical problems, including infection and electrolyte imbalance. In addition, infusion therapy services are invasive procedures which are painful and, when unnecessary, reduce the quality of a patient's life. Finally, Medicare compensated SNFs for these types of claims that should not have been paid.

Title XVIII of the Social Security Act (the Act), section 1862(a)(1)(A), states that no payment may be made under Part A or Part B of Medicare for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

To illustrate, an 80-year-old skilled nursing patient was transferred from a SNF to a hospital. While in the hospital, the patient had a gastronomy tube placement to assist in eating. When the patient returned to the SNF, he was started on tube feedings. Even though he was tolerating the tube feedings well, a nurse who worked for the infusion supplier evaluated the patient for intravenous feeding within days of his return from the hospital. Based on her patient evaluation, the infusion nurse contacted the facility doctor and recommended that infusion services be started. The facility doctor authorized the IV feedings. The PRO

physician who performed a medical review of the claim determined that the IV feedings were not necessary because the patient had a gastronomy tube and was taking the gastronomy tube feedings without difficulty. The PRO physician also concluded that this patient's health was placed at risk.

Costs Were Misclassified

The SNFs we reviewed misclassified infusion costs on their cost reports. Specifically, charges for nursing services and charges for equipment, such as infusion pumps and poles, were classified as ancillary instead of routine, despite a fiscal intermediary's determination that the costs should be treated as routine. Infusion costs were misclassified because the infusion suppliers misrepresented items on the invoices and provided misinformation to the SNFs about the treatment of the costs.

Before the adoption of PPS, the reasonable cost of ancillary services and capital-related expenses were paid in full. Routine operating costs were paid on a reasonable cost basis as well; however, they were also subject to per diem limits. Sections 1861(v)(1)(A) and 1888 of the Act authorized the Secretary to set limits on the allowable routine costs incurred by a SNF.

The Provider Reimbursement Manual, HCFA Publication 15-1, sections 2203.1 and 2203.2, defines ancillary and routine costs for SNFs. Drugs are defined as ancillary, whereas reusable equipment, such as infusion pumps and poles, are defined as routine. The Provider Reimbursement Manual does not explicitly state whether infusion nursing costs are routine or ancillary. However, for items not explicitly classified, the Provider Reimbursement Manual requires the provider to comply with the prevailing practice in the geographic area. In 1994, Mutual of Omaha, a Medicare fiscal intermediary, performed a survey and determined that the prevailing practice in Texas was for SNFs to classify infusion nursing costs as routine. Mutual of Omaha issued a Medicare newsletter to all its providers stating that nursing costs associated with infusion services were routine.

To market infusion services, the three infusion suppliers engaged in practices that permitted SNFs to bill nursing services as ancillary costs, contrary to the Medicare newsletter. In addition, the infusion suppliers attempted to conceal the routine costs from the fiscal intermediary by misrepresenting invoices that they submitted to the SNFs.

- One infusion supplier provided a cost report consultant as part of its standard infusion services contract. The cost report consultant advised SNFs that all infusion services, including nursing services, were ancillary.

- The same infusion supplier began charging $25 per nursing visit for its SNFs that filed claims with Mutual of Omaha as a result of Mutual of Omaha's newsletter. However, the supplier paid its nurses more than $25 per visit. The shortfall was

made up by increasing the price of the infusion drugs that the SNF was charged. The infusion supplier did not charge for the nursing visits for its SNFs that filed claims with Blue Cross of Texas, another Medicare fiscal intermediary. These SNFs were charged even higher prices for drugs.

- Marketing representatives from an infusion supplier informed prospective SNF clients that nursing services were free. The supplier was able to provide the "free" services by increasing the price of the infusion drugs.

- Another infusion supplier did not charge SNFs for nursing services. To cover the cost of the nurse, this supplier increased the price of infusion drugs by $110 per bag.

- Finally, another infusion supplier had a policy to charge $50 per nursing visit. However, the invoices that this supplier provided to SNFs disguised the $50 nursing charges as "ancillary supplies."

As a result of the misrepresentations, Medicare reimbursed the SNFs for costs that should have been classified as routine costs. These costs should have been subject to the routine cost limits. Instead, by claiming them as ancillary costs, there was no cost limit.

Monetary Impact of Unnecessary and Excessively Priced Infusion Services

Of the $9 million in audited claims submitted by 22 SNFs, $4.8 million in claims were not medically necessary. An additional $332,000 in payments that were found to be medically necessary were questioned because the prices exceeded the prevailing rate. Finally, another $158,000 was questioned because routine costs were misclassified on the cost report as ancillary costs.

One of the three infusion suppliers we reviewed has entered into a $10 million settlement agreement to resolve its civil liability under the False Claims Act and Civil Monetary Penalties Law which involved delivery of infusion services in Texas and in other States. The other infusion suppliers and many nursing homes are the subjects of additional audits and investigations by the OIG, the fiscal intermediary, and/or the Federal Bureau of Investigation.

Adoption of PPS

Section 4432(a) of the BBA required implementation of a Medicare PPS for SNFs. In 1998, HCFA implemented PPS for SNFs for cost reporting periods beginning on or after July 1, 1998. The PPS rates were based on mean SNF costs for the cost reporting periods beginning in FY 1995.

Since the adoption of PPS, concerns have been raised that reimbursement levels for high-cost services, including infusion therapy, are too low. Consequently, quality of care may be compromised. Various alternatives for changing PPS rates are being discussed, including establishing infusion therapy as a "carve-out" service. Under this approach, all costs associated with the service would be reimbursed similar to the Medicare SNF reimbursement system in place before 1998. Other alternatives include pending legislation which would increase the PPS rates for certain high-cost services, including infusion therapy. Another proposal is to change the base year for establishing PPS rates from 1995 to 1997. Underpinning these alternatives is an assertion that the 1995 base year does not accurately represent increases in patient acuity that occurred at SNFs during 1996 through 1998. While infusion therapy charges did increase significantly after 1995, these increases cannot be attributed solely to increased acuity levels. In fact, we are concerned that increases in infusion therapy charges over this period may have been dramatically impacted by the abusive practices described in this audit report.

CONCLUSION AND RECOMMENDATIONS

While our audit did not focus on the accuracy of the PPS rates for infusion therapy, we want to bring the results of our audit work to your attention should HCFA decide to change the reimbursement rates. We believe the adoption of PPS should help to correct the problem of SNFs and suppliers engaging in abusive billing schemes to increase Medicare reimbursements. However, PPS rates that do not reasonably reflect the SNFs' costs of providing services could still result in financial windfall to the SNFs. Under PPS, patients may still be subjected to unnecessary services. This could occur if unnecessary infusion therapy services were performed which may increase the patient's classification of services to a higher payment level within the PPS structure. Thus, more patients may be harmed by unnecessary infusion therapy.

We are concerned that HCFA may not have made adjustments for unallowable infusion therapy costs prior to the implementation of PPS.[3] The three infusion suppliers audited accounted for at least $138 million, or approximately 20 percent of all infusion therapy costs incurred by Medicare nationwide during 1995 through 1998.[4] Because the infusion therapy suppliers employed the same billing practices with hundreds of other SNFs in several States, we are concerned that additional unallowable costs were paid by Medicare

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[3]The issue of improper payments being included in the SNF PPS base year period costs was previously reported in our report entitled, "Review of the Health Care Financing Administration's Development of a Prospective Payment System for Skilled Nursing Facilities" (Report A-14-98-00350 dated July 1998).

[4]Between 1995 and 1998, SNFs charged Medicare a total of $1.4 billion for infusion therapy services. When SNFs billed Medicare for ancillary services, the SNFs would markup the direct costs they incurred to establish the Medicare charge. Generally, the markup was 100 percent of the direct costs. Accordingly, direct costs associated with infusion therapy services were about $700 million. The $138 million billed to SNFs by the three infusion therapy suppliers thus equates to about 20 percent of the total direct costs.

during 1995 through 1998. We also have concerns that these abusive practices may have resulted in inflated base year costs upon which the PPS rates were based. Furthermore, we believe reimbursement levels for infusion therapy that are too high affect quality of care due to overutilization, just as low reimbursement affects quality of care through underutilization. Therefore, before the PPS rates for infusion therapy are modified, we believe that the unallowable costs identified in this report should be seriously considered.

Accordingly, we recommend that HCFA:

- consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF PPS rates. In addition, if legislative changes are adopted which mandate the use of cost reimbursement for infusion services, work with the OIG to quantify a possible national error rate for infusion therapy services;

- identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS; and

- direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

HCFA COMMENTS AND OIG RESPONSE

In response to our draft report, HCFA generally agreed with our recommendations. In response to part of one recommendation, HCFA raised concerns about the benefit of establishing a national error rate for a set of services that is bundled with other sets of services into a single per diem rate under PPS. To take into account HCFA's comments, we changed our report to recommend a national error rate calculation in the event that Congress adopts legislation which mandate the use of cost reimbursement for infusion services. The complete text of HCFA's response is included as Appendix A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

DATE: OCT 27 '99

TO: June Gibbs Brown
Inspector General

FROM: Michael M. Hash
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report, "Infusion Therapy in Skilled Nursing Facilities," (A-06-99-00058)

Thank you for the opportunity to review the above-subject report that examines infusion therapy services provided to Medicare-reimbursed skilled nursing facilities (SNFs) prior to the implementation of the Prospective Payment System (PPS).

The OIG found that all three of the infusion suppliers reviewed charged SNFs excessive prices for infusion therapy, provided unnecessary infusion services to SNF patients, and improperly billed SNFs for nursing services that the SNFs, in turn, misclassified on the Medicare cost reports. The findings raise concerns that these abusive practices may have resulted in inflated base year costs upon which the PPS rates were based.

The report makes convincing case that, in the past, medically unnecessary infusion therapy services were furnished to the extent that they became a threat to patient safety. We agree with the OIG that medically unnecessary infusion services could lead to patients being harmed. The health and safety of our beneficiaries is a paramount concern of the agency.

The report demonstrates that problems of over utilization are common in a cost reimbursement system. In recognition of the vulnerabilities inherent in such a system, the Congress required the Health Care Financing Administration (HCFA) to implement a PPS for SNFs. HCFA began to implement the new PPS on July 1, 1998, and all Medicare-participating SNFs were paid under this system before July 1, 1999.

Taken by itself, the PPS may still encourage overuse of services. For this reason, we issued new medical-review guidelines to our fiscal intermediaries to assess whether services were reasonable and necessary as they determine whether a payment was made properly. In addition, HCFA recently published new medical review guidelines regarding Medicare's new SNF PPS, and we plan to hold related training in the current fiscal year.

Because we have instituted a new payment system which departs quite significantly from the old, cost reimbursement payment system, we believe it is essential to gain a more complete understanding, as soon as possible, of the nature and distribution of any payment errors being made. Hence, we have instructed our contractors to concentrate their efforts on random review of claims, and plan to use those results to focus additional efforts.

If we find problems in therapy use or other areas during these random reviews, we will move quickly to instruct contractors to focus on those problem areas. This will ensure that we devote appropriate resources to therapy use, as the report recommends.

Our specific comments on the report recommendations follow:

OIG Recommendation
HCFA should consider the impact of improper payments for infusion therapy services before making any refinements or updates to the PPS rates.

HCFA Response
We concur. While the report utilizes a relatively small sample, it nevertheless raised important questions concerning the appropriateness of the delivery and historical pricing of infusion therapy services in SNFs. It will be important for HCFA to consider the issues raised as work on refinements to the SNF PPS case mix adjustment progresses. In fact, HCFA is using standardized measures of pricing in its research on the refinements to the PPS.

OIG Recommendation
HCFA should work with the OIG and the fiscal intermediaries and Medicare Integrity Program contractors to quantify a possible national error rate for infusion therapy services, and to identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS.

HCFA Response
We concur in part. We will recover overpayments where appropriate. However, regarding quantifying a possible national error rate for infusion therapy services, establishing and tracking an error rate for a particular service (such as infusion therapy) would not be beneficial from a payment perspective. Each SNF PPS case-mix category (i.e., Resource Utilization Group) bundles all applicable services furnished to a beneficiary into a single per diem rate. As a result, all services furnished in a group are bundled into SNF prospective payment categories and all services are reviewed for appropriate utilization and coverage. To establish a national payment error rate and

tracking system for the particular service that is included within a payment category (and if denied may not adjust a payment level) would not significantly generate a medical review benefit.

OIG Recommendation

HCFA should direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

HCFA Comment

We concur. Since May 1999 we have directed our contractors to perform medical review of SNF PPS claims on a random basis (Transmittal NO. 99-20, "Payment Safeguard Review of SNF Prospective Payment Bills"). We, therefore, believe that all facilities will be at risk of being selected for review, and that those patients receiving infusion therapy will be reviewed for appropriate utilization levels.

R-1

CONFIDENTIAL

Etopophos®

(NDC 0015 - 3404 - 20)

(etoposide phosphate) for Injection

Launch Plan

Anticipated Launch: September/October 1995

BRAND POSITIONING STATEMENT:

Etopophos® (etoposide phosphate) for Injection is a water-soluble prodrug of etoposide which displays identical activity to the parent compound. The solubility of Etopophos in aqueous solutions provides distinct benefits over etoposide. Etopophos can be infused over as few as 5 minutes without causing hypotension and can be admixed in concentrations as high as 20 mg/mL. Etopophos represents a significant advance in the clinical and practical utility of podophyllotoxin derivatives.

"5/20"

(Five minute infusions/20 mg/mL concentration)

Larry J. Lunak
September 6, 1995

Executive Summary

In 1983, Bristol-Myers introduced VePesid® (etoposide) for Injection to the oncology community. In the 10 years in which the brand enjoyed domestic exclusivity, VePesid grew to become the highest selling cytotoxic in the United States. The year 1993 marked the apex of VePesid injectable growth with net sales in excess of $188 MM. With a strong clinical database and over a decade of experience, etoposide ranks as one of the most valuable agents available to today's clinicians in the fight against cancer.

The year 1987 saw the introduction of VePesid® (etoposide) capsules. Providing etoposide in a convenient oral form, VePesid capsules allowed clinicians to take advantage of a growing body of clinical data that, by 1990, suggested chronic, low dose exposure to etoposide provides a measurable benefit over traditional three day intravenous dosing. In 1993, VePesid capsules produced net sales of approximately $20 MM. Fueled in part by the Medicare Cancer Coverage Improvement Act, 1994 net sales of VePesid Capsules grew over $5 MM to $25.6 MM -- a 27 percent growth over 1993.

Together, VePesid capsules and injectable reached total net sales of $208 MM in 1993. Aside from setting the brand and divisional sales record in that year, 1993 also marked two very important changes in the VePesid Market -- the introduction of three new VePesid vial sizes (150 mg, 500 mg, and 1 gram) and, more importantly, the loss of the compound's exclusivity protection on November 11, 1993.

Although actual generic competition did not become a reality until February 14 of 1994, it had been anticipated as early as November of 1993. In expectation of such competition, BMOD instituted an aggressive partnering program with individual hospitals and Group Purchasing Organizations (GPOs) to support continued brand loyalty in the face of generic competition. Through the seemingly tireless work of the Bristol Laboratories Oncology Products sales force, over 1,500 hospitals and nearly 70 percent of all oncologists' office practices enrolled in BMOD's VePesid programs.

As a result of generic competition, final net sales for VePesid for Injection fell to $108.4 MM in 1994. Although at first glance this $72 MM drop seems dramatic, the $108.4 MM figure is quite respectable in light of market conditions. Facing nearly a full year of competition, the brand lost only 42 percent of its 1993 net sales. This loss was nearly evenly split between lost units (approximately 20 percent) and reduced net sales price (also approximately 20 percent). In addition, hospital groups having signed VePesid contracts

during 1993 received as much as 1.2 months of VePesid during the last week of December. Contractees signed during 1994 also received equivalent amounts of free VePesid. As a result, net sales figures actually underestimate the amount of VePesid successfully channeled into the marketplace in 1994.

Despite its overwhelming acceptance by the oncology community, etoposide as a clinical compound has several drawbacks. The molecule has a very **low water solubility** and must be produced in a non-aqueous form for parenteral administration. To achieve a pharmaceutically elegant product, etoposide **must be formulated with a variety of excipients** (citric acid, ethanol, benzyl alcohol, modified polysorbate 80, and polyethylene glycol). As a consequence of its formulation, VePesid must be administered over 30 to 60 minutes to decrease the patient's risk of experiencing excipient-induced hypotension. As a result of etoposide's low water solubility, VePesid admixtures **cannot exceed 0.2 to 0.4 mg/mL** without running the risk of the product precipitating. Also, the excipients used in the manufacture of etoposide injection produce a **physio/chemical reaction with acrylic and ABS polymers** which precludes the product's use with many chemo safety devices.

Etopophos® (*etoposide phosphate*) for Injection eliminates many of these concerns. A phosphate ester of etoposide, Etopophos is readily water soluble. Being highly water soluble, Etopophos can be manufactured as a *lyophilized powder,* avoiding the use of the various excipients which impart many of the negative attributes of etoposide for injection. Thus, etoposide phosphate can be administered over as few as *five minutes,* can be admixed at concentrations as high as *20 mg/mL* (compared to a maximum concentration of only 0.4 mg/mL for etoposide), and the formulation will not interact with acrylic and ABS polymers often used in chemotherapy admixture safety devices.

Etoposide phosphate is a *pro-drug* of etoposide. Upon parenteral administration, etoposide phosphate is rapidly and completely cleaved by circulating plasma phosphatases to yield etoposide. Thus, Etopophos eliminates the vast majority of etoposide's formulation drawbacks while still providing identical pharmacokinetic/pharmacodynamic properties.

Providing etoposide in the form of a phosphate ester results in a larger molecular weight for the compound. In fact, etoposide's molecular weight is 13.6% higher than the parent compound. As a result, Etopophos will be presented in single-dose vials containing 113.6 mg of etoposide phosphate -- a dose equivalent to 100 mg of etoposide. Since the drug becomes -- for all practical purposes -- etoposide once administered each vial will be treated by the admixing professional as a 100 mg vial of etoposide.

Exclusivity for the compound is assured through 2007. However, therapeutic substitution

of VePesid® (etoposide) for Injection and its generic competitors will continue to negatively impact upon Etopophos. Etopophos' physio/chemical attributes will serve as powerful differentiating feanures which should favor brand selection. In fact, BMS market research has shown Etopophos can maintain a premium price in the etoposide market. However, it must be noted that this premium differential falls as the market price for generic etoposide falls.

The Etopophos New Drug Application (#20-457) was submitted to the FDA for consideration on June 28, 1994. During the Agency's 45-day filing meeting the application was deemed to be "fileable." In addition, since the Etopophos NDA does not go beyond indications currently existing for the parent compound, the Agency determined the application need not undergo review by the Oncology Drugs Advisory Committee (ODAC). Based upon these facts, the FDA's Division of Oncology Drug Products initially anticipated completing their review of the application by year end, 1994. However, this did not come to pass. **Approval is now anticipated in an August to September 1995 timeframe.**

Upon launch, positioning strategy will stress the clinical equivalency of Etopophos to etoposide. The advantages of the brand (i.e., the ability to administer over as few as five minutes, the ability to admix at concentrations up to 20 mg/mL without risking precipitation, etc.) will be emphasized to justify the brand's premium price. Lastly, the financial advantages of conversion from etoposide to Etopophos will be stressed.

Appendix I. outlines a comparison of Etopophos and etoposide. This comparison and the brand positioning statement appearing on the cover of this plan represent the main thrust of the positioning strategy.